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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,350	10/15/2004	James Barder	12123-0003US	2345
22902	7590	08/21/2007	EXAMINER	
CLARK & BRODY			NGUYEN, CAMTU TRAN	
1090 VERNON AVENUE, NW			ART UNIT	
SUITE 250			PAPER NUMBER	
WASHINGTON, DC 20005			3772	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.	Applicant(s)	
10/511,350	BARDER, JAMES	
Examiner	Art Unit	
Camtu T. Nguyen	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 22 December 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-18 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) 3 and 10-18 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

*Response to Amendment*

The Office Action is in response to applicant's amendment filed on December 22, 2006.

Claims 1, 4, and 5 have been amended.

The Examiner is confirming with applicant's understand of the broadest interpretation with regards to the alternative recitation represented by conditions A or B. In other words, the Examiner is interpreting applicant's claim 1 of a condom having a vasodilator active compound applied to the external surface thereof and being coated with a lubricant, condition A includes the vasodilator disposed on the external condom surface in a form or condition B includes the vasodilator disposed on the external condom surface within a composition.

Applicant asserted that claim 1 has been amended to show immiscibility applied to both conditions and that such amendment introduced no new matter. The Examiner respectfully disagrees in view of the 112 1<sup>st</sup> paragraph rejection.

Applicant's comments pertaining to the references applied in the previous Office Action are acknowledged however deem moot in view of the following rejections.

*Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

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### ***Claim Objections***

Claim 3 and 10-18 are objected to because the recitation "a carrier material" in claim 3 and the recitation "a skin enhancer" in claims 10-18 appear to synonymous, according the specification, on the last paragraph of page 1, and the 3<sup>rd</sup> paragraph of page 5.

The last paragraph on page 1 reads "the vasodilator may be applied as a composition which includes a carrier material..." and on the 3<sup>rd</sup> paragraph of page 5, it reads "the active compound or compounds optionally together with skin enhancers may be applied direct to the appropriate region of the condom or as a composition dispersed or dissolved in a suitable carrier media, for example a gel carrier comprising a liquid medium and a thickening agent. According to another aspect of the invention, therefore, a composition for application to the external surface of a condom after unrolling on an erect penis comprises a vasodilator active compound and a carrier material."

Appropriate correction is required.

For purposes of interpreting this objection in view of applicant's specification, the carrier material is the skin penetration enhancer such as a gel carrier, the carrier material or the skin penetration enhancer is miscible with the vasodilator active compound, which is consistent with applicant's specification on the last paragraph of page 1.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In applicant's specification, as originally filed, applicant discloses a vasodilator active compound disposed and retained in the region towards the open end of a condom (page 1, 4<sup>th</sup> paragraph), more specifically, the same active compound may be contained or impregnated in or coated on the external surface of the condom (page 1, last paragraph). Applicant further discloses a second scenario where condom is coated with a lubricant, in which a vasodilator active compound may be dispersed or dissolved in the lubricant (see page 1, last paragraph) but preferably is disposed on the condom surface in a form or within a composition which is immiscible with the lubricant. With that understanding, claim 1 recites a condom having a vasodilator active compound applied to the external surface thereof and being coated with a lubricant. Clearly, "being coated with a lubricant" puts this recitation with the second scenario (presented above). With the second scenario (presented above), the specification shows support for the vasodilator active compound dispersed or dissolved in the lubricant. Claim 1 further recites the vasodilator active compound disposed on the external condom surface in the form, the form is immiscible with the lubricant. Clearly, this recitation is in contrast with the specification, as originally disclosed. For purposes of rejecting this limitation, the Examiner is interpreting this limitation to be consistent with applicant's specification, as originally filed, which supports the vasodilator active compound dissolved in the lubricant, making it miscible with the lubricant.

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Claims 9 and dependent claim 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the limitation "as a layer or coating in a polar elastomer in solution", in that context is not supported by the specification. On the first paragraph in page 3 applicant discloses the active compounds such as organic nitrates solution in the form of aqueous dispersion applied to the condom but does not discloses the organic nitrates applied to the condom in the form of a layer or a coating.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the vasodilator active compound preferably disposed on the condom surface with a composition, does not reasonably provide enablement for the vasodilator active compound preferably disposed on the condom surface in a form (see page 1, last paragraph. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification discloses the compound preferably is disposed on the condom in a form. What does applicant mean by "a form"?

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-4, 8-13, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby et al (U.S. Patent No. 6,737,084) and further in view of Kemp (U.S. Patent No. 6,840,244). Crosby discloses a composition for enhancing or treating female sexual response, the composition can be administered by a condom, e.g. by applying the composition to the condom prior to use in combination with other lubricants (column 5 lines 29-33). Crosby further discloses that the same composition can further comprise other active agents including vasodilators agents (column 5 lines 42-48). Crosby further discloses the composition can further comprise any pharmaceutically acceptable carrier (column 5 lines 58-60) but are not limited to water, emulsions (column 6 lines 1-3) but does not teach the composition is immiscible with the lubricant, as recited in claim 1. Kemp discloses an erectogenic compounds that can be incorporated into the condom including vasodilators, including the nitrates (column 2 lines 60-63). With regards to the lubricant, as recited, the Kemp reference discloses that the condom also includes a lubricant, preferably the lubricant is immiscible with the erectogenic compound or the composition containing the erectogenic component (column 4 lines 31-34). Therefore it would have been obvious to one skilled in the art to modify the Crosby et al's device such that its composition is immiscible with the lubricant as taught by Kemp for the purposes of the Crosby et al's composition resisting translocation from the external surface to adjacent portion of the internal surface when the condom device is in its rolled-up arrangement. With regards to claims 3, 10-13 and 17, the Kemp reference discloses the erectogenic compound and optionally a skin penetration enhancer may be dissolved in a medium (column 5 lines 17-19 and abstract). With regards to claim 4, the references applied above does not teach the lubricant having a pH value

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between 3 and 5; however, it would have been obvious to one skilled in the art to use a lubricant having a pH value between 3 and 5 as such would have prevented hydrolysis of the vasodilator active compound. With regards to claim 9, one skilled in the art would have recognized nitroglycerin, another vasodilator, is an organic nitrate. Nitroglycerin is well known and widely used for improving or increasing blood flow.

Claim 5-7 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby et al (U.S. Patent No. 6,737,084) modified by Kemp (U.S. Patent No. 6,840,244) above, and further in view of Solanki et al (U.S. Patent No. 6,182,661). Crosby discloses a composition for enhancing or treating female sexual response, the composition can be administered by a condom, as applied above, but does not teach the condom includes a textured region on the external surface, at least towards the open end of the condom. Solanki et al discloses in Figures 1-5 a latex condom (1) comprising textured region with projections (6) towards the open end (2) of the condom (1). Therefore, it would have been obvious to one skilled in the art modify the Crosby et al's condom to include textured regions with projections (6) as such would provide sensation. With regards to 7, the common material used to make condoms is either from rubber latex, or a synthetic rubber-like, such material would inherently display miscibility with the vasodilator

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Camtu Nguyen

August 9, 2007

*Patricia Bianco*  
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*8/19/07*